

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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JUN 01 2010

PATENT INFRINGEMENT AND RACKETEER INFLUENCE & CORRUPT ORGANIZATION (RICO)

AT 8:30
WILLIAM T. WALSH, CLERK

Dr. George Pieczenik, Pro Se

Plaintiff

v.

Idexx Reference Laboratories, Inc., Zymogenetics, Inc.
Zymogenetics, LLC, Millenium Pharmaceuticals, Inc.,
Invitrogen Corporation, Howard Hughes Medical Institute,
Centocor Ortho Biotech Products, L.P., Centocor Ortho
Biotech Services, Centocor Ortho Biotech, Inc.,
Inc., Amgen USA Inc., Amgen Inc, GE Healthcare
Biosciences Bioprocess Corp, GE Healthcare Strategic
Sourcing Corporation, GE Healthcare Inc., GE Healthcare
Bio-Sciences Corp., Dyax Corporation, International
Business Machines Corporation, Forest Laboratories, Inc.,
Gilead Sciences, Inc., Genzyme Corporation, Allergan
USA, Inc., Johnson & Johnson, Baxter Diagnostics Inc.
Abbott Laboratories., Abbott Laboratories. Inc., Biogen
Idex Inc., Biogen Idec U.S. Corporation, Ortho-McNeil
Pharmaceutical, Inc., Ortho-McNeil, Inc., Ortho-McNeil
Janssen Scientific Affairs, LLC, PerkinElmer Health
Sciences, Inc., The Dow Chemical Company (Delaware),
The Dow Corning Corporation, The Dow Agrosciences LLC,
Schering Berlin Inc., Schering-Plough Products, Inc.,
Schering Corporation, Schering-Plough Biopharma,
Schering-Plough International, Inc., Wyeth Pharmaceuticals
Inc., Wyeth Holdings Corporation, Corning Incorporated,
OSI Pharmaceuticals, Inc., Onyx Pharmaceuticals, Inc.
and John Does 1 through 61.

CIVIL ACTION NO 10-cv-02327-FLW-TJB

REPLY TO DYAX'S MOTION TO DISMISS

Defendants

REPLY TO DYAX'S MOTION TO DISMISS

BACKGROUND

1. Whereas, Plaintiff Pieczenik's '363 patent is a pioneering patent in the area of combinatorial chemistry. The patent was filed in 1985, with a disclosure document 118831 filed on July 11, 1983. (Exhibit A). This predates any patent or publication in the then newly created area of combinatorial chemistry. The foreign patent was filed Aug. 28, 1986 and published in 1987 as WO/ 87/01374. (Exhibit B) This foreign publication made this pioneering technology available in detail to Dyax scientist Ladner in 1987. Ladner sites Pieczenik's foreign patent in his patent 7,208,293, 6,979,538, *inter alia*. (Exhibit C, D).
2. Whereas, Bruce Merrifield is the father of solid state peptide chemistry and Nobel Laureate describes Plaintiff Pieczenik pioneering invention in the following terms "Dr. George Pieczenik filed a master combinatorial chemistry patent on August 28, 1985. This WIPO(87/01374) publication date is March 12, 1987. This filing is prior to any

other patent filing and/or publication in this area. I believe it will take precedence over any of the several patents on combinatorial chemistry filed subsequently.

The patent claims random nucleotide libraries that code for random peptide libraries separately and on display phage. It also claims random monoclonal and polyclonal libraries and the use of combinations of the two in a matrix to identify molecular surfaces, antibody specificity, lead compounds for drug discover, receptors and antigenic determinants.

This general field has expanded explosively during the past six years and has created great excitement among academic and industrial chemists and biologists. Several companies have been founded solely for the purpose of developing the synthetic process and exploring the commercial potential of the libraries. It holds great promise for drug discovery in the pharmaceutical industry. I know of no other scientific breakthrough that has a potential of such magnitude.

I have known Dr. Pieczenik since 1972 when he worked in my laboratory at the Rockefeller University and later with Dr. Norton Zinder's laboratory her at Rockefeller. Dr. Pieczenik is ahightly intelligent and most imaginative scientist. He has several other "firsts" in a range of discilines. He has also published some very important papers, for example on on the Origin of Protein Synthesis in 1976 with three major figures in science, Francis Crick, Sidney Brenner and Aaron Klug.

I reiterate that this master patent on combinatorial chemistry is extremely important." Exhibit E

3. The '363 patent has no prior art in terms of previous patents or publications. This qualifies it as a "pioneering patent" in combinatorial chemistry.
4. Whereas, Plaintiff Pieczenik filed an *Amicus Curiae* brief (Exhibit F) in the Supreme Court of the United States in the *Chakrabarty v Diamond* case as the only single inventor. This brief had been cited by the Court in its decision. and it explains that the chemical DNA is "resurrectable" as a viable and variable coding for an organism. Therefore, the metes and bounds of the definition of a recombinant molecule should include the selection procedure for its isolation. This decision states that which is patentable should "include anything under the sun that is made by man" Pioneering patents in this new area therefore have the "glow of the sun"
5. Early Supreme Court decisions gave broad protection to pioneering patents and limited protection to improvement patents. *Evans v Eaton* 20 US 356, 399-407(1822). The doctrine of equivalents was applied broadly to pioneering patents.
6. A modern definition of a pioneering patent is one which "first..disclose(s) a basic operational concept", an improvement patent is one which issues "in a crowded art." *Hughes Aircraft v United States* 717 F.2d 1351, 1362 (Fed.Cir. 1983).
7. In *McCormick v. Talbott*, 61 US 402(1857) the Court used an "as a whole" analysis to protect original inventors and an "element by element" analysis for inventors of improvements. This case is important in that it points out that an "improvement" patent such as the Ladner/Dyax patents cannot use the "doctrine of equivalents" to suppress all other improvements. This is what Dyax with its portfolio of "improvement" patents has tried to accomplish. This should be encouraged..
8. The Supreme Court created a standard for employing the doctrine of equivalents. The first step was to classify the patent as a pioneering patent or an improvement patent in relation to the prior art. *Westinghouse v Boyden Power Brake Co.* 170 U.S. 537 (1898). Given this criteria, the Pieczenik 363 patent is a "pioneering patent" and the Ladner/Dyax patents are "improvement patents".
9. There is a lesser standard that allows one to invoke the doctrine of equivalents to not just "pioneering patents" but also to "patents of merit". *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30 (1929). This lesser standard need not apply as the '363 patent is a "pioneering patent".
10. In *Roche Palo Alto LLC v Ranbaxy Laboratories Limited* Case Number 3:2006 cv 02003, Judge Wolfson suggests that it is the Plaintiff's burden to raise the theory of infringement under the doctrine of equivalents. This theory is hereby invoked.

11. Background on the Science- Clinical Utility of "Biologics"

12. As the '363 patent was a pioneering patent, it was very much ahead of its time. The idea that one could make combinatorial libraries of nucleotides, peptides and antibodies was considered just an interesting academic exercise with no clinically useful applications. These products were called "biologics" and one class of these "biologics" was monoclonal antibodies. This won a Nobel prize and was suggested to the laureate by Plaintiff. John Sedat's was a witness to this suggestion and he is Elizabeth Blackburn's husband, who was also aware of Plaintiff's suggestion (Exhibit G). She won this year's Nobel prize. The conventional wisdom was that only "drugs" are clinically useful and "biologics" which would have to be infused were too complicated to be clinically useful.
13. Imclone changed that whole perspective,. Imclone and Lilly now take a license with Pieczenik on his '363 patent. Imclone pioneered the use of Erbitux, as a treatment for various cancers. Now there are many "biologics" to treat various systemic disorders and cancers.
14. Therefore, now the '363 patent is a method for creating more precise and specific biologics which can be used clinically. This took 15 years for FDA approval. If the '363 patent didn't take 14 years to issue and then have 17 years after issuance viability this case would be moot. This patent was filed pre-GATT.
15. Plaintiff Pieczenik's first two patents on single stranded DNA sequencing vectors expired before the genome sequencing project started. These vectors and his patent strategy were extensively used in sequencing the human genome.
16. One concern which Plaintiff had wished to address was a legal definition of the metes and bounds of a "combinatorial library". At present, the CAFC has not addressed this issue in spite of Plaintiff's attempts in his filings. A clear definition of the metes and bounds of a combinatorial library, which is similar to but quite different than a Markush group, would simplify patent filings for both the Plaintiff and Defendants in this and many future cases. The closest the CAFC has gotten to defining a combinatorial library rests on the issue of whether the term "having" is open or closed. Historically, "having" was an "open" term much like the term "comprising" being an "open" term versus "consisting" being "closed". This would allow one to interpret combinatorial libraries having a defined number of variants to include the carrying sequences. Otherwise, combinatorial claims can be obviated by simply adding one nucleotide or one amino acid. This would defeat the purpose of even trying to claim inventions relating to combinatorial libraries.

Haley and Harnett's *Res Judicata* Arguments

17. In general, Opposing Counsel, Ropes & Gray's motion to dismiss is very similar to Ropes & Grey's recent filings to dismiss Cold Spring Harbor Laboratory's suit (Exhibit H) against Ropes & Grey for plagiarism and malpractice. (Exhibit I).
18. For Ropes&Gray, in their Motion to Dismiss the Cold Spring Harbor malpractice and plagiarism suit, to argue, with a straight face, that plagiarism is not only good but the normal standard in patent filings among IP lawyers and that it has no real consequence in patent prosecution is incredible *chutzpa*, *prima facie*.
19. However, I have known Ropes & Gray's James Haley and Chris Harnett, (when they were with Fish&Neave) for many years now and I have never known either one to submit plagiarized papers. In fact, James Haley correctly informed me when I accused them of "sewer service" which did not allow me to file an opposing reply that he in fact had sent the papers to my counsel at the time, Dreier & Baritz. Unfortunately, my counsel never so informed me. (I shall address the issue of Dreier in following paragraphs). Chris Harnett has sometimes elaborated the facts, such as awarding *sua sponte*, in Shira Scheindlin's Court, a "doctorate" to his client making him "Dr. Fordyce".
20. The only other point of contention with Haley and Harnett is their attempted use of Wacław Szybalski as their expert witness. Wacław Szybalski made the Wieg

typhus vaccine on Jewish mathematicians in Lwov, Poland for the Waffen SS during WWII (Exhibit J). This vaccine was tested on inmates in Buchenwald, Block 54.

21. This witness plus Fish & Neave's filing all of Henry Ford's (an outspoken anti-Semite) patents clearly upset Plaintiff, as a child of Holocaust survivors. I have a feeling that both Haley and Harnett regret having suggested Wacław Szybalski as an expert witness.
22. I will state that James Haley has the integrity of the old school of patent litigators and that Chris Harnett under his direction tries very hard to maintain that standard. This is clearly a standard that has collapsed at Ropes&Gray. James Haley understood clearly that I did not care to prevail in the lower courts but wished to bring my arguments for a definition of "combinatorial libraries" to the Court of Appeals for the Federal Circuit. This was and still is necessary in order, to bring a guiding light for claim construction to all IP lawyers filing in this new area of "combinatorial chemistry" which the '363 patent created
23. Just for the reason given above I would like to keep James Haley and Chris Harnett in this case, and would hate to see them dismissed, to be able to once again to have the CAFC try and address the issue of defining the "metes and bounds" of a "combinatorial library".
24. It will take too many years, and as I have had two heart attacks, to train more opposing counsel in this area.
25. For this reason alone, I will forgo any request for financial damages and royalty payments from Dyax. However, given Haley and Harnett's argument that there is no inducement to infringe among the John Does 1-60, I would then request a list of their licensees and collaborators who are supposedly not "infringing" given their arguments under a discovery request or subpoena from this Court. This and a simple posting on the Dyax web site that the Pieczenik '363 patent and filing date is prior to Dyax patent filings would be a satisfactory resolution.
26. This request is similar to a settlement Plaintiff had negotiated with the MRC Laboratory of Molecular Biology, where they posted an acknowledgement of the Pieczenik '363 patent and its early filing, *inter alia*.
27. Haley and Harnett argue that the infringement by Dyax was already adjudicated in SDNY and in the Massachusetts Court. However, the only thing that was adjudicated in the SDNY was the issue of jurisdiction. Dyax prevailed in having the case transferred to its home court in Massachusetts. Haley and Harnett have not brought up the issue of jurisdiction in this reply, either personal or long-arm, and therefore one can presume that this will not be a primary defense.
28. Haley and Harnett argue that the Massachusetts Court analyzed only claims 24 and 34 of the '363 patent. It is with heavy irony that they claim Plaintiff Pieczenik was represented by "experienced counsel". During the Markman hearing, Plaintiff's counsel Michael Nicodema mistook amino acids for nucleic acids and visa versa. This was the first "biotech" patent Dreier&Baritz litigated.
29. Now, while Ropes&Grey seem to have reached a bottom in the ethics of patent filings, their behavior is nothing when compared to the behavior of the firm which represented me against Ropes&Grey, i.e. Dreier& Baritz.
30. My counsel was in collusion with various law firms which represented clients which infringed during the course of their "prosecution" of my patent. But even more dramatically, the lead counsel in this firm Marc Dreier, Yale A.B and Harvard Law, of Dreier & Baritz, is now in jail and the firm is dissolved. (Exhibit K.) Plaintiff's counsel defected to law firms representing infringers.
31. Therefore, both Ropes&Grey and Dreier&Baritz should be considered the "poster boys" for poor IP firms and their client representation.
32. That is why I would like to get a fresh start in this litigation. However, I need knowledgeable opposing counsel that will not have to go through 20 years of file wrapper and litigation to be up to speed. At this point, this is only Harnett and Haley. There is one other, but we will have settled before our first hearing.

33. That aside, the Markman ruling in the '363 patent only addressed claims 24 and 34. Both claims have a 10 per cent limitation on the combinatorial library size. This was the element that Dyax claimed was not part of their libraries. However, claims 1-6 and 23 have no 10 percent limitation on the combinatorial library and therefore in this very specific elemental analysis, Dyax products would have infringed literally. This is without even invoking the doctrine of equivalence for a pioneering patent.
34. Therefore, only two very narrow dependent claims were adjudicated by the Massachusetts court out of 92 claims on the '363 patent and 23 claims on the '448 patent (a continuation in part of the '363) (Exhibit L). There are no 10 percent limitations on any of the '448 claims.
35. Therefore, *res judicata* does not apply to all the other claims, which are both broader and should be considered "as a whole".
36. As an example, of direct infringement, it is a fact that New England Biolab (NEB) collaborates with Dyax and NEB supplies Dyax with three combinatorial libraries NEB has created. NEB takes the identical license with Pieczenik, that Dyax has with NEB, except it is 1/3 the amount that Dyax receives. Exhibit M,N,O.
37. All three libraries have a legal insert which states clearly: "Legal - Licenses/Patents/Disclaimers: Ph.D.TM is a trademark of New England Biolabs, Inc. This product is sold for research use only and not for resale in any form. Commercial use of this product may require a license. For license information under U.S. Patent No. 5,866,363 please contact the Licensing Office, New England Biolabs, Inc., 240 County Road, Ipswich, MA 01938. Commercialization of sequences discovered using this product may require a license from Dyax Corp. under U.S. Patent Nos. 5,223,409, 5,403,484 and/or 5,571,698 and associated patent rights. For license information contact the Director of Corporate Development, Dyax Corp., One Kendall Square, Bldg. 600, Cambridge, MA 02139, Fax 617-225-2501"
38. It is a fact that Dyax uses and modifies New England Biolabs libraries. NEB advertizes these as being combinatorial libraries of 7 amino acids, 12 amino acids and a constrained 7 amino acids respectively. All three combinatorial libraries are literally defined by nucleotide and amino acid library claims 1-92 in the '363 as well as the patent claims "as a whole". The '363 patent is the pioneering patent, the Ladner '409,484, 698 are innovative patents. Dyax is still required by NEB agreement with Plaintiff to contact NEB to obtain a license from Plaintiff under the 5,866,363 patent as it has and still uses the NEB libraries.
39. One can argue, the doctrine of patent exhaustion, but that issue has not been raised and will be raised in Plaintiff's litigation with Monsanto and its contractual obviation of the doctrine of patent exhaustion in its harassment of farmer re-planting genetically modified seeds.
40. Dyax has recently entered the area of combinatorial libraries of antibodies and the mapping of epitopes of such libraries. These combination of antibody libraries and epitope mapping procedures are covered under claims 8, 14,23,48, 79 and 90-92, *inter alia* of the '363 patent and, therefore, these new products and processes infringe the metes and bounds of the '363 patent, in the literal specific and "taken as a whole".
41. This court has as much jurisdiction over this infringement case as the Massachusetts forum had previously. Plaintiff is a citizen of NJ and Dyax has commercial contacts in NJ i.e. Imclone, Route 202, *inter alia*.
42. Haley and Harnett argue that "no reasonable jury" could find any of the contested elements. However, the *Warner-Jenkinson* decision does not use a "reasonable person or jury" argument but "persons reasonably skilled in the arts". This "skilled in the arts" is a quite important distinction from the "reasonable person" perspective. Bruce Merrifield is a "person reasonably skilled in the arts" (see above). His analysis of the pioneering nature of this patent should have considerable weight in having this patent treated "as the whole" and not as an innovation patent

where element by element analysis is required. *Warner Jenkinson Co., Inc. v. Hilton Davis Chemical Co.* (95-728), 520 U.S. 17 (1997).

43. Several years have passed since the first litigation and new art has evolved as has "persons reasonably skilled in the arts". Considering that at the time the '363 patent was filed, there were only a very limited number of persons skilled in the art, times have changed and the area of combinatorial chemistry has expanded exponentially as the number of persons "skilled in the arts" of combinatorial chemistry.
44. Haley and Harnett incorrectly argue that the second case in the SDNY based on the '448 patent (Exhibit L) was adjudicated on the merits of the claims. In reality, Dyax and counsel were dismissed prior to any adjudications. They were once again dismissed simply because of jurisdictional arguments.
45. Harnett incorrectly states issues and reasons for the Pfizer decision in the second case in the SDNY. The second case was before Judge Shira Scheindlin. Pfizer was dropped by Plaintiff, unilaterally, when Judge Scheindlin said she would have to recuse herself as she had Pfizer stock. Plaintiff felt it was more important to stay in her Court and elected to drop Pfizer. Therefore, there was no issue at bar in respect to Pfizer in Judge Shira Scheindlin's court. (Exhibit P, transcript). Also, the Scheindlin Court mandated a mediation making Plaintiff's motion for mediation moot.
46. Harnett was out of the case when Judge Shira Scheindlin allowed Merck, Ag, which was selling Erbitux in Europe on a contract of adhesion with Imclone to be brought into her court on a RICO. Plaintiff Pieczenik demonstrated that Merck, Ag was never de-nazified by the McCloy committee. Merck, Ag was involved in the methylene blue injections in the eyes of concentration camp inmates. Similar arguments will be presented in the case of Bayer, *inter alia*.
47. However, I accede to Haley and Harnett's request to dismiss the RICO charges. Whatever, conspiracy or crimes Dyax, Ropes&Grey may have committed, they have made a convincing argument that it does not come up to the level of a RICO. I am not sure this RICO charge should not be applied *nunc pro tunc* to my ex-counsel Marc Dreier. But he has enough troubles already in jail.
48. However, I contend that Dyax in its use and modification of NEB's libraries infringe the '363 patent and its epitope mapping of combinatorial antibody libraries requires that Haley and Harnett remain in this case. As consideration, for my needing trained and honorable opposing counsel, I drop all requests for financial remuneration and royalties against Dyax.
49. However, given the arguments that Dyax does not induce infringement, it is therefore reasonable to ask that their licensees, collaborators and signers of contracts-not-to-sue i.e. the John Does 1-60, be given to Plaintiff under discovery or by subpoena which they also argue do not infringe. Therefore, there should be no issue in their minds of exposing this list to any serious and effective prosecution for infringement.
50. Thirdly, Haley and Harnett are both aware that the Pieczenik '363 patent is the first filed patent in combinatorial chemistry. It has a 102(e) "snap-back" filing date to 1985. A statement similar to the MRC Laboratory of Molecular Biology statement on their web site should be posted on the Dyax web site for the life of the '363 patent. This is both equitable, honest and has some old school IP integrity.

Respectfully Submitted,
//Dr. George Pieczenik



Dated: May 29, 2010

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Proof of Service:

I, hereby, affirm that an electronic copy of this Reply and Exhibits have been emailed to all counsel of record as of today on 5.29.2010. A paper copy is to be Mailed by Express Mail after Memorial Day during to Opposing Council Arnold B.Calmann, at Saiber,LLC, One Gateway Center, 10th Floor, Newark, New Jersey 07102-5311, 973-622-3333. Two paper copies will be left with the Court after Memorial Day. One for the Clerks Office and One as a Courtesy Copy for Judge Freda L. Wolfson.
E. Mail copies were sent to the following on 5.29.2010

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